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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/165,460	10/02/98	RINE J	0972/006002

HM12/0913

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EXAMINER	
TUNG, P	
ART UNIT	**PAPER NUMBER**
1652	11

DATE MAILED: 09/13/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/165,460	Applicant(s) Rine et al.
	Examiner Peter Tung	Group Art Unit 1652

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *10-13, 15, 17-19, and 22-30* is/are pending in the application.

Of the above, claim(s) *15, 25, 29, and 30* is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *10-13, 17-19, 22-24, and 26-28* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *5*

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

1. Claims 10-13, 15, 17-19, 22-30 are pending.

2. Applicant's election without traverse of Group III, claims 10-13, 17-19, 22-24 and 26-28 in Paper No. 7, dated 4/27/00 is acknowledged.

3. Claims 15, 25, 29 and 30 are withdrawn from further consideration as being drawn to a non-elected invention.

Specification

4. The following CRF errors were corrected by the STIC Systems Branch:

Sequence 4- moved (ix) FEATURE: id (ii) MOLECULE TYPE: section above (xi) SEQ DESCRIPTION heading.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 10-13, 17-19, 22-24 and 26-28 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for vectors comprising SEQ ID NO: 1 or 2, nucleic acid sequences which encode polypeptides of SEQ ID NO: 3 or 4 or host cells transformed with said vectors, does not reasonably provide enablement for vectors comprising

nucleic acid sequences which encode polypeptides of SEQ ID NO: 3 or 4 containing conservative substitutions or host cells transformed with said vectors. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the relative skill of those in the art, (6) the predictability or unpredictability of the art, and (7) the breadth of the claims. The breadth of the claims encompass a vector encoding either SEQ ID NO: 3 or 4 with any number or conservative amino acid substitutions. While guidance is provided on what amino acids are considered conservative substitutions, insufficient guidance is provided on where conservative amino acid substitutions can be made in the amino acid sequence of SEQ ID NO: 3 or 4 without affecting the function of the protein. Insufficient examples are provided of the proteins comprising SEQ ID NO: 3 or 4 and conservative amino acid substitutions where the proteins still have enzymatic function. The skill of those in the art is low in determining where conservative amino acid substitutions can be made in an enzyme without affecting enzymatic activity as there is unpredictability in the art of making even conservative amino acid substitutions to an enzyme and knowing how such changes will affect

enzymatic activity. Undue experimentation would be required to enable the full scope of the claims based upon the limiting scope of the disclosure.

7. Claims 11 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for vectors comprising the nucleic acid sequences of SEQ ID NO: 1 or 2, does not reasonably provide enablement for vectors comprising conservatively modified variations of SEQ ID NO: 1 or 2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the relative skill of those in the art, and (6) the breadth of the claims. The breadth of the claim encompasses any number of changes to SEQ ID NO: 1 or 2. Insufficient guidance and insufficient examples are provided on what changes are made to SEQ ID NO: 1 or 2 which would be considered conservative modifications. As the skill of those in the art is low in determining how to use a polynucleotide if it does not encode a particular protein, one of skill in the art would not know how to use such a vector comprising SEQ ID NO: 1 or 2 comprising conservative modifications as the disclosure only teaches SEQ ID NO: 1 and 2 encoding the proteins of SEQ ID NO: 3 and 4, respectively.

Undue experimentation would be required to enable the full scope of the claims based upon the limiting scope of the disclosure.

8. Claims 11-12, 17-19, 22-24 and 26-28 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The instant claims are drawn to a vector comprising DNA encoding polypeptides of SEQ ID NO: 3 or 4 comprising conservative substitutions and transformed host cells. However, only the polypeptide sequence of SEQ ID NO: 3 and 4 and the DNA sequence of SEQ ID NO: 1 and 2 have been disclosed. The specification and claims do not indicate what distinguishing attributes are shared by the members of the claimed genus of a vector comprising DNA encoding polypeptides of SEQ ID NO: 3 or 4 comprising conservative substitutions. The scope of the claim includes numerous chemical species with widely differing structural, chemical and physical characteristics and the genus is highly variable because a significant number of structural differences between genus members is permitted. The specification and the claims do not provide any guidance as to what is essential to the operation and function of the claimed vector comprising DNA encoding polypeptides of SEQ ID NO: 3 or 4 comprising conservative substitutions and what characteristics could distinguish compounds in the genus from others in the genus are missing from the disclosure. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variable, a single disclosed member of the genus is insufficient to describe the

genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus of a vector comprising DNA encoding polypeptides of SEQ ID NO: 3 or 4 comprising conservative substitutions. *see University of California v. Eli Lilly and Co. 43 USPQ2d 1398.*

9. Claims 26-28 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The cells in claims 26-28 with the specified characteristics must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If a deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements. *See 37 CFR 1.808.* Further, the record must be clear that the deposit will be maintained in a public depository for a period of 30 years after the date of deposit or 5 years after the last request for a sample **or for the enforceable life of the patent whichever is longer.** See 37 CFR 1.806. If the deposit has not been made under the Budapest treaty, then an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such

assurances, or a statement by an attorney of record over his or her signature must be made, stating that the deposit has been made at an acceptable depository and that the criteria set forth in 37 CFR 1.801-1.809, have been met. Applicant's attention is directed to *In re Lundak*, 773 F.2d. 1216, 227 USPQ 90 (CAFC 1985), and 37 CFR 1.801-1.809 for further information concerning deposit practice.

10. Claims 10-12, 17-19, 22-24 and 26-28 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The instant claims are drawn to a polynucleotide or SEQ ID NO: 1 which encodes a polypeptide of SEQ ID NO: 3. However, it does not appear that the polypeptide of SEQ ID NO: 3 is encoded by the polynucleotide of SEQ ID NO: 1. Therefore the Applicant was not in possession of a polynucleotide which encodes the polypeptide of SEQ ID NO: 3.

11. Claims 26-28 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection. The instant claims of cells with specific characteristics comprising a polynucleotide which hybridizes to a polynucleotide which encodes SEQ ID NO: 3 or 4 is not supported in the instant specification. The specification does not identify the use of these particular cells as host cells for said polynucleotides.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 12, 17, 18, 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rose et al. in view of Nozaki et al. (U.S. Patent No. 4,997,767). Rose et al. teach a polynucleotide which is 99.1% identical to a polynucleotide which encodes SEQ ID NO: 3. Such a polynucleotide sequence would be expected to hybridize to a polynucleotide encoding SEQ ID NO: 3 under stringent conditions. Rose et al. do not teach a vector comprising said sequence or host cells comprising said vector. Nozaki et al. teach (Col. 2, lines 45 to Col. 3, line 60) a yeast

shuttle vector for expressing proteins in yeast which can replicate in both E. coli and in yeast. Nozaki et al. do not teach a vector comprising a polynucleotide which hybridizes to a polynucleotide encoding SEQ ID NO: 3 or prokaryotic and yeast cells transformed with said vector. It would have been obvious to one of ordinary skill in the art at the time the invention was made to produce vectors, as taught by Nozaki et al., comprising the polynucleotide taught by Rose et al., for the benefit of replicating said vector in E. coli and transforming yeast with said vectors and thereby obtaining yeast for expression of the protein encoded by the DNA taught by Rose et al. One of ordinary skill in the art is motivated to combine the two references as Nozaki et al. teaches a vector for expressing proteins in yeast where the vector can also replicate in E. coli. Rose et al. teach a DNA sequence which encodes a protein where said DNA sequence can be used in the vector taught by Nozaki et al. One of ordinary skill in the art would have a reasonable expectation of success at doing this as the use of shuttle vectors for replicating DNA and expression is well known in the art. Therefore the invention as a whole would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made.

14. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rose et al. in view of Sambrook et al. Rose et al. teach a polynucleotide which is 99.1% identical to a polynucleotide which encodes SEQ ID NO: 3. Such a polynucleotide sequence would be expected to hybridize to a polynucleotide encoding SEQ ID NO: 3 under stringent conditions. Rose et al. do not teach a vector comprising said sequence or host cells comprising said vector. Sambrook et al. teach (page 16.3-16.6, "Expression of Proteins from Cloned Genes") mammalian cells transformed with

mammalian expression vectors. Sambrook et al. do not teach a vector comprising a polynucleotide which hybridizes to a polynucleotide encoding SEQ ID NO: 3 or mammalian cells comprising said vector. A mammalian cell comprising a vector, as taught by Sambrook et al., comprising a polynucleotide which hybridizes to a polynucleotide encoding SEQ ID NO: 3, as taught by Rose et al., would have been obvious to one of ordinary skill in the art at the time the invention was made. One of ordinary skill in the art is motivated to combine the two references as Sambrook et al. teach mammalian cells transformed with an expression vector for producing proteins and Rose et al. teach a DNA sequence which encodes a protein where said DNA sequence can be used in the expression vector taught by Sambrook et al. One of ordinary skill in the art would have a reasonable expectation of success at doing this as expressing proteins in mammalian cells is well known in the art. Therefore the invention as a whole would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made.

15. No claims are allowed.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter Tung, Ph.D. whose telephone number is (703) 308-9436. The examiner can normally be reached on Monday-Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy, Ph.D., can be reached on (703) 308-3804. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

PONNATHAPU ACHUTAMURTHY
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

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REFERENCE   1  (bases 1 to 1825)
  AUTHORS   Rose,M., Koetter,P. and Entian,K.D.
  JOURNAL   Unpublished
REFERENCE   2  (bases 1 to 1825)
  AUTHORS   MIPS.
  TITLE     Direct Submission
  JOURNAL   Submitted (25-SEP-1995) Data collected by MIPS on behalf of the
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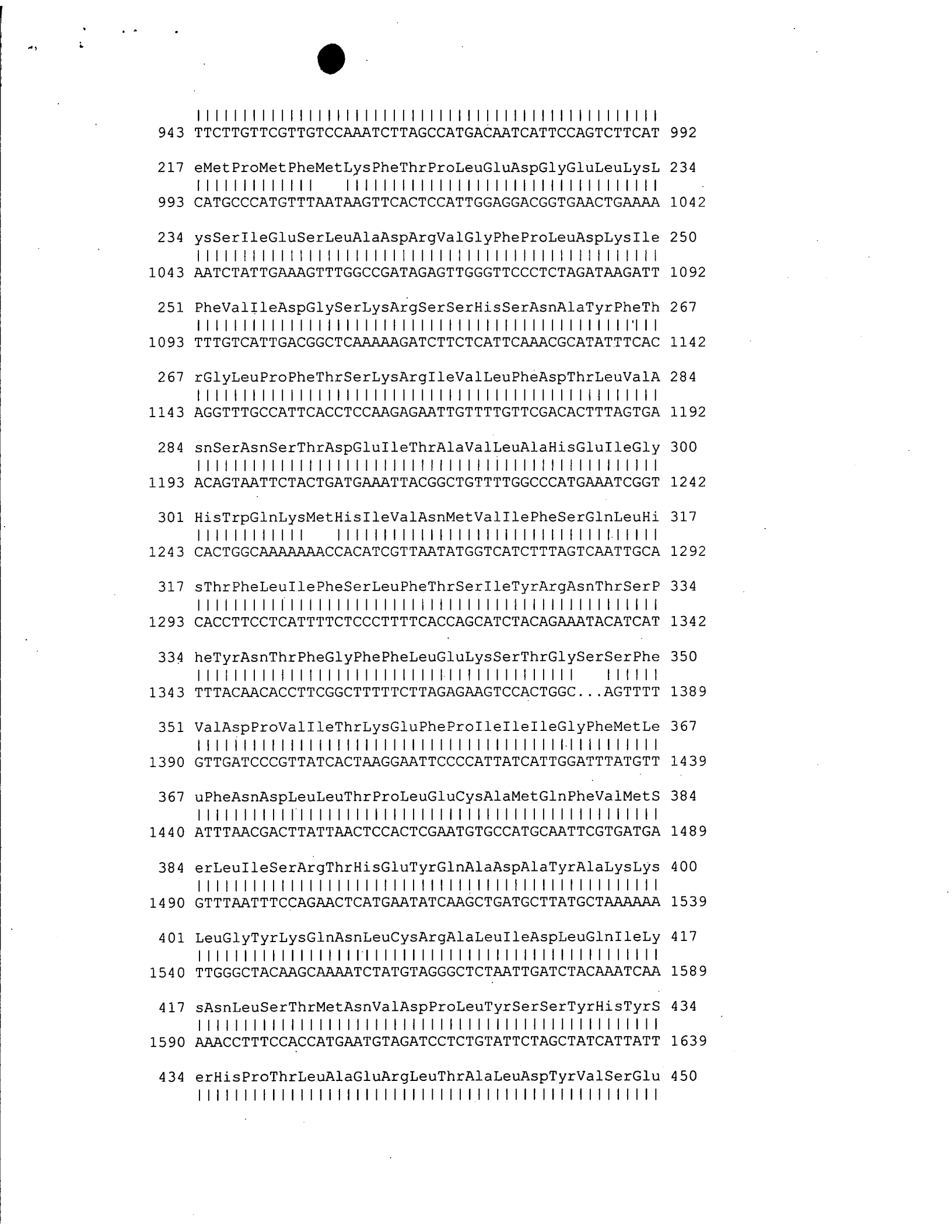

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ORGANISM Saccharomyces cerevisiae
Eukaryota; Fungi; Ascomycota; Hemiascomycetes; Saccharomycetales;
Saccharomycetaceae; Saccharomyces.
REFERENCE 1 (bases 1 to 1825)
AUTHORS Rose,M., Koetter,P. and Entian,K.D.
JOURNAL Unpublished
REFERENCE 2 (bases 1 to 1825)
AUTHORS MIPS.
TITLE Direct Submission
JOURNAL Submitted (25-SEP-1995) Data collected by MIPS on behalf of the
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Max-Planck-Institut fuer Biochemie, Am Klopferspitz 18a D-82152
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Qy    480 CCACCTGTGCTGGAAGACGAAATTGATGATGAAACTTTTCATAAATCAAGGAACTACTCC 539
          ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db    481 CCACCTGTGCTGGAAGACGAAATTGATGATGAAACTTTTCATAAATCAAGGAACTACTCC 540

Qy    540 CGGGCCAAGGCCAAGTTCTCCATTTTCGGTGACGTCTATAACCTAGCCCAAAAGCTAGTT 599
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Qy    600 TTCATCAAATACGACCTCTTCCCTAAAATCTGGCACATGGCCGTTTCTTTATTGAATGCA 659
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Db    601 TTCATCAAATACGACCTCTTCCCTAAAATCTGGCACATGGCCGTTTCTTTATTGAATGCA 660

Qy    660 GTCCTGCCAGTCAGATTTCATATGGTCTCCACTGTCGCACAGAGTTTTATGCTTCTTGGG 719
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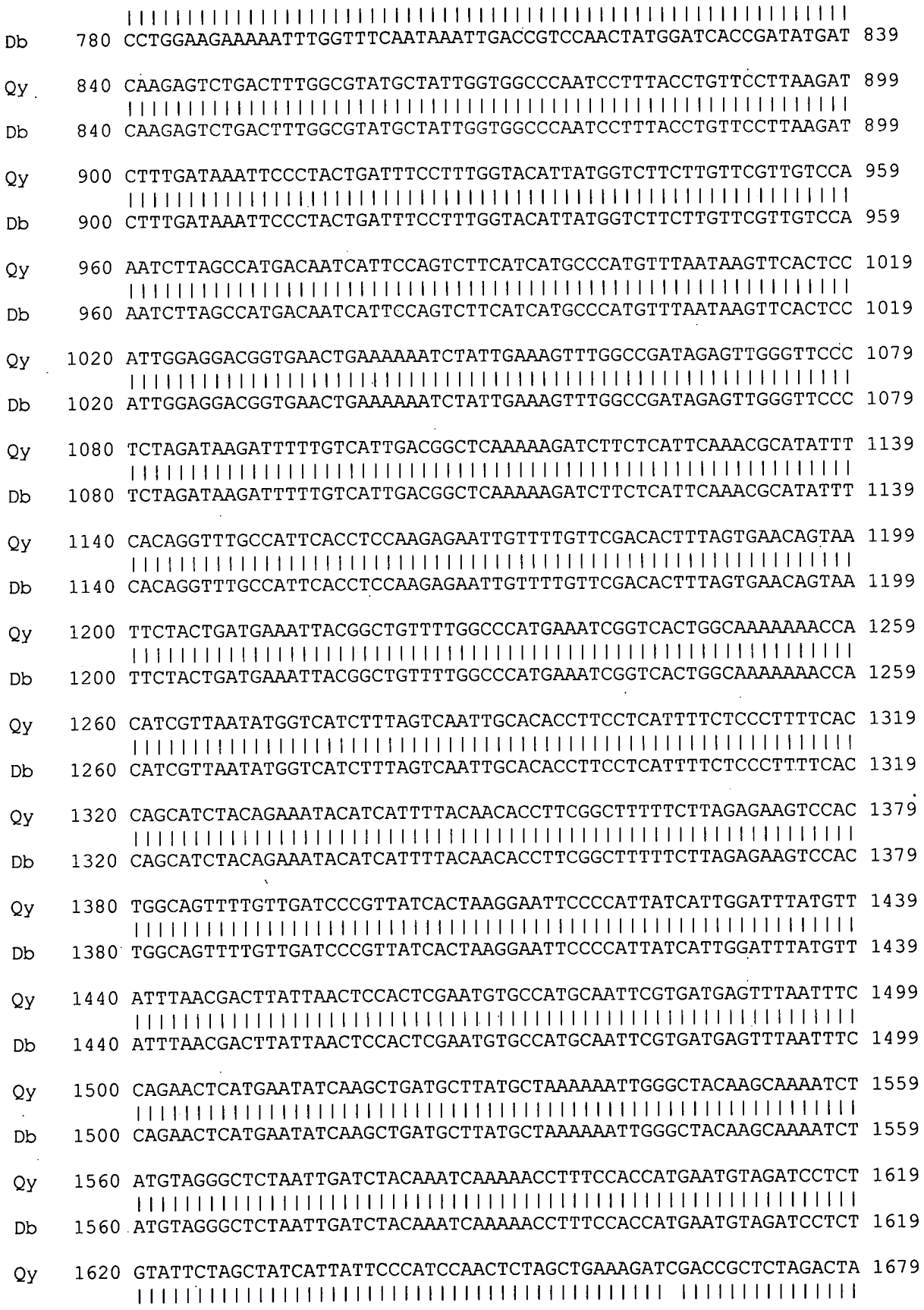

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Qy    1800 AAAGAAAAAATAAACGATTAAACATT 1825
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